

- 2) Claims 1-3, 7, and 9 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Langer (1995, Clin. and Exper. Hypertension, 17(7): 1127-1144) and Udell (Information About Conjugated Linoleic Acid, published by Soft Gel Technologies Incorporated).

1. Claim 9 is not indefinite.

Claim 9 is rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite, as the Examiner asserts that the "Applicants left out the measurement unit for the lower ranges of 0.1" (Office Action, page 2).

The Applicants have reviewed Claim 9, both in the specification as it was filed and as it was listed in the Response to Office Action Dated December 8, 2000 and Election of Species (filed on January 5, 2001), and in both documents the phrase "to 20 grams" appears after the phrase "about 0.1". Thus, Claim 9 reads:

9. The method of Claim 1 wherein said safe and effective amount of conjugated linoleic acid is about 0.1 to 20 grams.

✓ The Applicants are therefore puzzled as to the reason for the Examiner's assertions, and respectfully submit that Claim 9 as filed is not indefinite, on the ground that both the range and the measurement unit are clearly present in the claim. Therefore, the Applicants respectfully request that the rejection of Claim 9 as indefinite be withdrawn.

2. Claims 1-3, 7, and 9 are not obvious.

Claims 1-3, 7, and 9 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Langer (1995, Clin. and Exper. Hypertension, 17(7): 1127-1144) and Udell (Information About Conjugated Linoleic Acid, published by Soft Gel Technologies Incorporated). The Examiner asserts that Langer teaches a method to reduce blood pressure by losing weight, and that Udell teaches CLA for weight loss, and then concludes that it would have been obvious "to use CLA in the method of reducing blood pressure by losing weight of Langer to achieve the beneficial effect of weight loss by taking CLA in view of Udell" (Office Action, page 3). The Applicants respectfully traverse on several grounds.

objection
Udell
teaches
wt. loss
by fatty
CLA

First, the references do not teach what the Examiner assert that they do. Udell does not teach "CLA for weight loss;" in contrast, the reference states that CLA "actually helps to significantly decrease body fat, while balancing the ratio between fat and lean muscle mass" (Udell, last page). Decreasing body fat may not result in weight loss, especially if the fat is replaced by muscle tissue. Udell further states that "CLA will provide just the balance your fitness and weight loss formulations need," which is a **suggestion** that CLA be added to

objection
Langer
teaches
on
p 1132
lines 9-10

existing formulations, not a **statement** that CLA causes weight loss. Langer does not teach a method to reduce blood pressure by losing weight. Langer describes several **risk factors** for hypertension, which include alcohol intake, dietary minerals, weight, and sodium intake (pages 1131-1132). The reference further states that data from clinical trials "suggest that considerable weight must be lost for an individual to significantly reduce blood pressure," and that few people achieve and maintain such a weight loss (page 1132). The effect of the weight loss could be due to effects on other risk factors, such as the metabolism of alcohol or minerals.

good
to
learn

Second, the Examiner has not established a prima facie case of obviousness. A *prima facie* case of obviousness is a three-pronged test. First, there be a suggestion or motivation to combine the references, in the references themselves or in the art generally, but NOT from the Applicants' invention (MPEP § 2143). Second, there must be some reasonable expectation of success should the claimed combination be effected. And third, each claim element must be disclosed or taught in the combined references (MPEP § 2143). The Examiner has not met all three prongs for even one claim. Failure to establish **any one** of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicants to allowance of the claims in issue. See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

1) There Is No Motivation to Combine the References

yes
motivation
is
provided

The Examiner asserts that a person of ordinary skill in the art would be motivated to combine Langer and Udell to result in the claimed invention. The Examiner, however, is improperly considering these references collectively **before** establishing the threshold requirement that a person skilled in the art would be motivated to combine these references in the first place. The Applicants submit that the references **cannot** be considered collectively

until the Examiner points to some motivation to combine these references. The purpose of this threshold requirement is to prevent the Examiner from using the invention itself and hindsight reconstruction to defeat the patentability of the invention. The Federal Circuit articulates this position when it states:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claims. *In re Rouffet et al.*, 149 F.3d 1350, 1357 (Fed. Cir., 1998).

The Examiner does not "show reasons" why one skilled in the art would be motivated to combine these references, but instead merely points to the desirability of the claimed combination by making a conclusory statement. However, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of doing so. (MPEP § 2143.01, citing to *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

The Examiner provides no suggestion or motivation in the references or in the prior art to make the combination. Thus, the Examiner has not met the first requirement for establishing a case of *prima facie* obviousness, and for this reason alone Claims 1-3, 7, and 9 are not obvious over the cited references. Therefore, the Applicants therefore respectfully request that the rejection of the claims be withdrawn.

2) There is No Reasonable Expectation of Success

Furthermore, the Examiner has not provided any evidence that the cited combination would have had a reasonable expectation of success. The Applicants note that not all hypertension is associated with excess weight, nor is all excess weight associated with hypertension. There may exist a correlation, but that is not the same as a cause and effect. Is the Examiner suggesting that all drugs which effect a weight loss are automatically capable of decreasing hypertension? Until experiments demonstrate that a particular drug effects a reduction of hypertension, it cannot be predicted that it will have such an effect. Thus, the Examiner has not met the second requirement for establishing a *prima facie* case of

obviousness, and for this reason as well Claims 1-3, 7, and 9 are not obvious over the cited references. Therefore, the Applicants therefore respectfully request that the rejection of the claims be withdrawn on this basis as well.

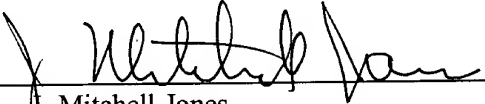
3) Not All of the Claim Elements are Taught or Suggested.

Finally, the Examiner has not indicated where in the cited references all of the claim elements are taught or suggested. For example, the Applicants cannot find where the references suggest administering a conjugated linoleic acid composition to a subject under conditions such that blood pressure of said subjects is reduced. Thus, the Examiner has not met the third requirement for establishing a *prima facie* case of obviousness, and for this additional reason Claims 1-3, 7, and 9 are not obvious over the cited references. Therefore, the Applicants therefore respectfully request that the rejection of the claims be withdrawn on this basis as well.

CONCLUSION

All grounds of objections and rejections of the Office Action of February 2, 2001 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call Mitchell Jones collect at (608) 218-6900.

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